REMARKS

This Amendment is in response to the Examiner's Office Action mailed on May 3, 2005. Claims 1-12 have been cancelled. Claims 13, 15, 17, and 20-27 are amended. The Examiner has allowed Claims 14 and 16. Claims 13-27 are pending in the instant application and under consideration.

I. Withdrawn Rejections

Applicants note with appreciation that the rejection of claims 13 and 17-19 under 35 U.S.C. 102(b) has been withdrawn.

Applicants further note with appreciation that the rejection of claims 13, 17-20 and 24 under 35 U.S.C. 103(a) has been withdrawn.

II. Rejection Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected Claims 13, 15, 17, and 20-27 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Responding to the Examiner's request for clarification of the term adeno-associated virus (AAV), claims 13, 15, 20, 22, 24, and 26 have been amended to clarify that the adeno-associated virus (AAV) nucleic acid sequence claimed therein is a nucleic acid sequence "wherein said AAV nucleic acid sequence comprises a rep gene or a cap gene or a rep gene and a cap gene." Applicants wish to thank the examiner for the suggested claim language, and believe that the term adeno-associated virus (AAV) nucleic acid sequence as used in the amended claims is definite so as to particularly point out and distinctly claim the invention.

The Office Action states on page 3 that the specification indicates that the full-length AAV sequence is about 4680 nucleotides, but that in the Examples, only 4235 nucleotides of the AAV sequence are introduced into the plasmid. Applicants wish to point out that an inventor is

not limited to claiming that which is disclosed in specific working examples. From the teaching in the patent application, a person of ordinary skill in the art would appreciate that an adeno-associated virus nucleic acid sequence as claimed would not be limited to the 4235 nucleotide sequence in the working example and could comprise the entire AAV nucleic acid sequence.

The Office Action also states that the specification does not make clear what is encompassed by rAAV. The term "rAAV," as referred to in the specification, stands for recombinant adeno-associated virus. This terminology was commonly used in the art at the time of the filing date of the above application as indicated by the references attached hereto in Exhibit A. Thus the term, 'rAAV' as well as "rAAV vector" and "rAAV viral particle", would be understood by one of ordinary skill in the art at the time of the invention, and the uses of the term recombinant in the specification and claims are consistent with the understanding such person skilled in the art would have for this term.

In the Office Action, it is stated that the specification defines the term "rAAV vector" in the following manner on Page 3, lines 3-5: "The expression "rAAV vector" comprises any AAV viral particle and its DNA, which may contain foreign DNA, except for that of a helper virus, which is necessary to develop AAV viral particles." The Office Action expresses discomfort with the use of the term "may" in this definition. However, it would be understood by one skilled in the art at the time of the invention that a *recombinant* vector could be made either by having foreign DNA inserted into the original DNA, or by removal (excision) of a portion of DNA from the original DNA. Therefore, one skilled in the art at the time of the invention, using his or her knowledge of the term recombinant, would understand that the recombinant vector *may* (or may not) contain foreign DNA. The Office Action also asserts that this definition could read on wild type AAV virus, but this is not the case; first, because "recombinant" indicates a change to the nucleic acid sequence; and second, because the language in each of claims 17, and 20-27 in which the term rAAV is used specifies that an AAV helper virus nucleic acid sequence is included in the nucleic acid sequence. Since wild type AAV virus does not have an AAV helper virus sequence, rAAV, as used in the claims cannot read on wild type.

The Office Action also refers to a potential a lack of insight provided by the statement in the specification on page 4, lines 9-10 that "the rAAV viral particle preparations distinguish themselves in that they contain no AAV wild type." At the end of this quote, the Office Action incorrectly adds the word "sequences" after wild type. There is no use of the word sequences in this paragraph of the specification, and it would be understood from the structure of the sentence that the term "wild type" here refers to viral particles and not sequences. The quoted language (without the term sequences) is consistent with the definition of rAAV in the specification, and is consistent with how the term "rAAV viral particles" would be understood by someone of ordinary skill in the art at the time of the invention. Therefore, as used in the specification, rAAV viral particle preparations containing no "AAV wild type" is consistent with subject matter of the invention.

The Office Action points to the use of the term "rAAV vector *commonly present in cells*" on page 2 line 24 of the specification. Applicants have identified a mistake made in the translation to English from the original patent application in German. The correct translation should be "being present together".

Applicants therefore request that the specification be amended. No new matter is introduced by this amendment.

Claims 17 – 19 are dependent on claims 13, 14, 15, and 16. Applicants believe that the amendments to claims 13 and 15 put claims 17 – 19 in condition for allowance in light of the fact that claims 14 and 16 have been allowed.

Applicants believe that this rejection is obviated and/or overcome in view of the amendment to the claims. Therefore, Applicants request that the above rejection be withdrawn.

III. Rejection Under 35 U.S.C. § 112, First Paragraph

The Examiner has rejected Claims 17, and 20-27 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

The Office Action states that the specification does not provide a written description of the rAAV structure. Applicants respectfully submit that as described above, "rAAV" stands for recombinant adeno-associated virus, and that the use of this term in "rAAV vector" and "rAAV viral particle" in the claims would be understood by one of ordinary skill in the art at the time of the invention to whom the term recombinant would be well known.

As described above, Applicants believe that the term "rAAV DNA" as defined in the specification on Page 3, lines 3-5: "The expression "rAAV vector" comprises any AAV viral particle and its DNA, which may contain foreign DNA, except for that of a helper virus, which is necessary to develop AAV viral particles," is consistent with the meaning that would be applied by one of ordinary skill in the art at the time of the invention for recombinant adeno-associated virus vector. It would be understood by one skilled in the art at the time of the invention that a *recombinant* vector could be made either by having foreign DNA inserted into the original DNA, or by removal (excision) of DNA from the original DNA. Therefore, one skilled in the art at the time of the invention, using his or her knowledge of the term recombinant, would understand that the recombinant vector *may* (or may not) contain foreign DNA. The Office Action also asserts that the definition could read on wild type AAV virus, but this is not the case; first, because "recombinant" indicates a change to the nucleic acid sequence; second, because the language in each of claims 17, and 20-27 in which the term rAAV is used specifies that an AAV helper virus nucleic acid sequence is included in the nucleic acid sequence. Since wild type AAV virus does not have an AAV helper virus sequence, rAAV, as used in the claims does not read on wild type.

The Office Action also describes a lack of purported insight provided by the statement in the specification on page 4, lines 9-10 that "the rAAV viral particle preparations distinguish

themselves in that they contain no AAV wild type." At the end of this quote, the Office Action incorrectly adds the word "sequences" after wild type. There is no use of the word sequences in this paragraph of the specification, and it would be understood from the structure of the sentence that the term "wild type" here refers to viral particles and not sequences. The quoted language (without the term sequences) is consistent with the definition or rAAV in the specification, and is consistent with how the term "rAAV viral particles" would be understood by someone of ordinary skill in the art at the time of the invention. Therefore, as used in the specification, the term "AAV wild type" in reference to viral particles, is not inconsistent with subject matter of the invention.

Applicants believe that this rejection is obviated and/or overcome in view of the amendment to the claims. Therefore, Applicants request that the above rejection be withdrawn.

IV. Rejection Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected Claims 20-27 under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps.

Claims 20-27 have been amended by adding a step. Applicants believe that the claims are now complete and that there are no omitted essential steps. Applicants believe that this rejection is obviated and/or overcome in view of the amendment to the claims. Therefore, Applicants request that the above rejection be withdrawn.

V. Informalities

Claims 17 and 20-27 are objected to because they use the abbreviation "rAAV". The claims have been amended to spell out the term *recombinant adeno-associated virus* the first time the abbreviation is used. Applicants therefore request that the objection be withdrawn.

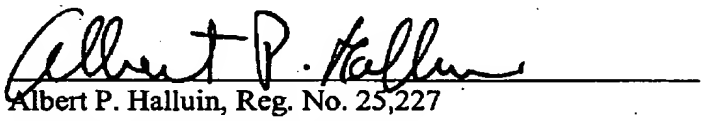
CONCLUSION

In view of the above amendments and remarks, the subject application is believed to be in good and proper order for allowance. Early notification to this effect is earnestly solicited.

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 565-3585. The Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit Account No. 23-2415 (Attorney Docket No. 31304-704.831) for any matter in connection with this response, including any fee for extension of time, which may be required.

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: August 29, 2005 By: 

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Enclosures: Exhibit A

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